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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/370,453	08/09/1999	DAN W. DENNEY JR.	GENITOPE-038	8128

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EXAMINER

BANSAL, GEETHA P

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 02/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



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09/370,453

Serial Number

Division

Examined Application

Attorney Docket No.

EXAMINER	
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DATE MAILED:

Below is a communication from the EXAMINER in charge of this application
COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

- a) ☐ is extended to run _____ or continues to run _____ from the date of the final rejection
- b) ☒ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).
- ☐ Applicant's response to the final rejection, filed _____ has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
- b. ☐ They raise new issues that would require further consideration and/or search. (See Note).
- c. ☐ They raise the issue of new matter. (See Note).
- d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☒ will be entered ☐ will not be entered and the status of the claims will be as follows:

Claims allowed: None

Claims objected to: None

Claims rejected: 1, 3-6, 25-32

However;

- ☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because Applicant's arguments are not persuasive to withdraw the obviousness rejection. write it is appreciated that Applicant's arguments regarding the non-obviousness of B-cell
5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented. Lymphoma is a rare

- ☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.
- ☐ Other

the rejection is directed against the presence of several such clones the making the lymphoma polyclonal. for Burkitt's lymphoma is a B-cell lymphoma which is polyclonal expansion of B-cells. by E. Brumpt.

GEETHA R. BANSAL
PRIMARY EXAMINER

BEST AVAILABLE COPY

Art Unit: 1642

DETAILED ACTION

1. Applicant's amendment filed August 9, 2000 (Paper No: 12) are acknowledged. Accordingly, claims 7-20 are cancelled. Claims 1-6, 21-24 are pending.

2. Applicant's election without traverse of Group II (claims 1-6) in Paper No. 2 is acknowledged.

Claim Rejections - 35 U.S.C. § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1, 2 are indefinite in that it is not clear if the multivalent vaccine is a molecule that comprises 2 Ig variable regions or is a composition which comprises different Ig molecules? i.e. are these vaccine molecules bispecific or multispecific molecules?

B. Claims 1, 2 are ambiguous in that it is not clear if the at least two different immunoglobulin molecules are expressed by the same B cells.

Claim Rejections - 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tao et al (1993). The claims are drawn to a multivalent vaccine comprising at least two recombinant variable regions of Igs from B cell lymphomas which express different idiotopes. Tao et al teach an idiotype/ granulocyte macrophage stimulating fusion protein (Id/GMCSF) as a vaccine for B cell lymphoma by obtaining heavy and light chain variable regions from B cell tumours. Tao also teaches that the idiotype protein can be coupled to cytokines such as GMCSF which augments antigen presentation, as well as mixing with an adjuvant to augment immune responses. Stevenson et al teach Ids expressed by B cell tumors present attractive vaccine candidates. Vaccination with Id induces protective immunity. Stevenson et al also teach genetic approaches that isolate v regions sequences encoding Id regions from tissue or biopsy specimens as well as assembly into single chain Fv (scFv) fragments, which can be expressed to produce recombinant proteins. Neither of these references teach 2 or more Ig with different idiotopes. It would have been prima facie obvious to a person of ordinary skill in the art at the time of the claimed invention to combine the teachings of the above references with the knowledge possessed by one of ordinary skill in the art to make a multivalent vaccine with more than one idiotope, as each B cell is known to produce a single species of Ig with a specified idiotope pattern. B cell lymphoma is well known to one of ordinary skill in the art to be a neoplastic condition that results in an abnormal growth and proliferation of B cells which express different idiotypes as a result of the

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polyclonal nature of the cells. One of ordinary skill in the art would have been motivated to produce a vaccine with more than one idiotope comprising the composition as a polyvalent vaccine is more effective in counteracting or killing of the different cell populations expressing different idiotopes and achieving a better therapeutic benefit.

8. No claim is allowed.

9. Papers related to this application may be submitted to Group 1642 by facsimile transmission. Papers should be faxed to Group 1642 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308-3995.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 13, 2000

GEETHA P. BANSAL
PRIMARY EXAMINER
Geetha P. Bansal